

**UNITED STATES PATENT APPLICATION**

of

**DANIEL A. MISER**

**CHONG WANG**

**JAMIE ANDERSON**

and

**MATTHEW R. LEWIS**

for

**COMPOSITIONS AND METHODS FOR  
PRESERVING PERSONAL CARE PRODUCTS**

**WORKMAN, NYDEGGER & SEELEY**  
A PROFESSIONAL CORPORATION  
ATTORNEYS AT LAW  
1000 EAGLE GATE TOWER  
60 EAST SOUTH TEMPLE  
SALT LAKE CITY, UTAH 84111

# COMPOSITIONS AND METHODS FOR PRESERVING PERSONAL CARE PRODUCTS

## CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority under 35 U.S.C. § 119(e) to U.S. provisional application Serial No. 60/391,757, filed June 26, 2002. For purposes of disclosure, the foregoing application is incorporated herein in its entirety.

## BACKGROUND OF THE INVENTION

### 1. The Field of the Invention

[0002] The present invention relates generally to all-natural compositions and methods for preserving personal care products. More particularly, the invention relates to the use of wasabi and its derivatives as a preservative for personal care products.

### 2. The Relevant Technology

[0003] Water-based personal care products, such as lotions and toners, provide an hospitable environment for microbial growth. Microbes can be introduced to personal care products, for example, during manufacture, storage, and/or consumer use. How quickly the microbes grow and render the product unsuitable for use is a function of various factors, including the susceptibility of individual products to microbial growth, the presence or absence of preservatives, and the storage condition of the personal care product after the microbial contamination first occurs.

[0004] As a result, personal care products have defined shelf lives to ensure a product's quality. These shelf lives typically include two critical dates: a shelf date, which is an

absolute limit on a product's life, regardless of whether the packaging is opened by a consumer; and an expiration date, which may be shorter than the shelf date, depending upon when the user opens the packaging. For example, a product may have a two year expiration date after a product is opened by a consumer, subject to an absolute shelf life of three years.

[0005] Obviously, the longer a product's shelf life the greater its value, both to a manufacturer concerned about product quality and maintaining inventories and to a consumer concerned about how quickly a product must be consumed. There is therefore a constant need to develop effective methods to deter microbial growth and thereby extend product shelf lives.

[0006] Typically, artificial preservatives are used to extend product shelf lives. There is a growing consumer awareness and fear, however, that artificial preservatives may contain damaging chemicals whose effect on users or the environment may be harmful, either individually over time or in a cumulative effect with other chemicals. There is therefore also a need for products that preclude microbial growth without the use of artificial preservatives. This presents a difficult challenge to providing "organic" and "all natural" products that nevertheless have suitable shelf lives.

[0007] One somewhat effective approach is to carefully package a product in sanitary conditions and then hermetically seal the product to prevent the introduction of microbes. This only prevents product degradation prior to consumer use, however, as an unpreserved product may quickly degrade after an initial consumer use, such as after microbial-laden fingers contact the product. Alternatively, intricate product dispensing

systems, such as pumps, may provide effective methods to delay contamination but cannot slow microbial growth once contamination occurs.

[0008] U.S. Patent No. 6,361,812 to Ekanayake et al. ("*Ekanayake*") discloses a preservative system for use in *e.g.*, foods, beverages, health care products, personal care products, herbicidal products, and containment devices, comprising one or more isothiocyanates and an artificial preservative selected from sorbate preservatives, benzoate preservatives, and mixtures thereof. The isothiocyanate compounds may be manufactured synthetically or isolated from natural plant matter.

[0009] In view of the foregoing, there is a continuing need for more organic and natural systems and compositions to preserve personal care products.

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A PROFESSIONAL CORPORATION  
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60 EAST SOUTH TEMPLE  
SALT LAKE CITY, UTAH 84111

## SUMMARY OF THE INVENTION

[0010] The present invention relates to personal care product preservation systems and methods that use wasabi japonica (“wasabi”) and, optionally, a co-preservative to preserve a personal care product. Wasabi has been found to provide a natural preservative effect that inhibits the growth of microbes that can otherwise flourish in aqueous based personal care products. The personal care products can be in any desired form, including emulsions, gels, serums, solutions, and other vehicles suitable for use with personal care products, such as toners, lotions, creams, cleansers, refiners, and the like. Unlike artificial preservatives, including synthesized compounds and single compounds isolated from natural products, wasabi is a true natural product.

[0011] Accordingly, in one personal care product preservation system according to the invention, a personal care product is blended with a preservative composition comprising wasabi and pentylene glycol. One preferred form of wasabi is wasabia japonica root extract. Suitable concentrations of the preservative may vary according to the personal care product formulation being preserved. For example, the concentration of water is often an important variable because microbial growth generally follows water concentrations. The pentylene glycol provides a co-preservative effect.

[0012] According to another embodiment of the invention, a personal care product preservation system comprises a personal care product and a preservative composition comprising wasabia japonica, undecylenoyl glycine, and capryloyl glycine. The undecylenoyl glycine and capryloyl glycine are collectively believed to provide a co-preservative effect. The use of other organic co-preservatives, including variations and derivatives of the foregoing, is also contemplated by the invention.

[0013] Similarly, a method according to the invention for inhibiting microbial growth in a personal care product comprises mixing a personal care product, a wasabia root japonica extract, and at least one additional co-preserved selected from the group consisting of pentylene glycol, undecylenoyl glycine, and capryloyl glycine.

[0014] These and other advantages and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

WORKMAN, NYDEGGER & SEELEY  
A PROFESSIONAL CORPORATION  
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## DETAILED DESCRIPTION OF THE INVENTION

### I. INTRODUCTION.

[0015] Personal care product preservation systems and methods comprise the use of *wasabia japonica* (“wasabi”) as a preservative to inhibit microbial growth in personal care products. The wasabi provides a natural preservative without the use of undesirable artificial preservatives. When used in selected concentrations and pH ranges and with appropriate co-preservatives, the wasabi can be an effective preservative.

[0016] The optional co-preservative, for example pentylene glycol or a mixture of undecylenoyl glycine and capryloyl glycine, helps preserve the personal care product and ensure that only safe levels of wasabi need to be used. The use of a co-preservative is important because certain personal care products may require high preservative concentrations to prevent all microbial growth. Because high concentrations of wasabi may cause skin irritation, the present invention uses co-preservatives to allow effective microbial growth control at low wasabi concentrations.

[0017] According to another embodiment of the invention undecylenoyl glycine and capryloyl glycine can be used without wasabi to inhibit microbial growth in personal care products. These two compositions have been found to have a synergistic effect that can provide an effective approach to inhibiting microbial growth.

[0018] The personal care products can be in any desired form including emulsions, gels, serums, solutions, and other vehicles. Such vehicles are commonly used in consumer products such as toners, lotions, creams, refiners, cleansers, and the like.

[0019] In addition to the surprising effectiveness of wasabi as a preservative for personal care products, wasabi has the advantage of being an all-natural product. In contrast,

conventional preservatives typically comprise synthetic chemical compounds, and are therefore disfavored by many consumers for their potential health and environmental risks. The use of wasabi as an alternative preservative to synthetic chemical compositions provides not only reduced health and environmental risks, to the extent that such exist, but also satisfies the consuming public's demand for natural products.

[0020] Additional advantages of the present invention will become readily apparent to those skilled in the art from the following detailed description, wherein currently preferred embodiments of the invention are shown and described in the disclosure. As will be realized, the invention is capable of other and different embodiments, and its several details are capable of modifications in various obvious respects, all without departing from the invention. Accordingly, the description is to be regarded as illustrative in nature, and not as restrictive.

[0021] In the following description, numerous specific details are set forth in order to provide a thorough understanding of the present invention. It will be obvious, however, to one skilled in the art that the present invention may be practiced without these specific details. In other instances, well known aspects of personal care products have not been described in particular detail in order to avoid unnecessarily obscuring the present invention.

## II. COMPOSITIONS

### A. Preservatives

[0022] According to the invention, the primary preservative is wasabia japonica ("wasabi"), a member of the cruciferae family. The wasabi plant grows about knee high, is semi aquatic, and produces a thickened stem in a similar fashion to a small brussel



sprout. As the stem grows the lower leaves fall off. This stem has a very pungent smell and flavor when made into a paste, which is commonly used as a condiment for sushi. Wasabi can be produced both as a ground grown or water grown plant, although water-grown plants generally produce a higher quality product than the ground grown plants.

[0023] Like its relatives in the cabbage family, wasabi owes its pungency to isothiocyanates. In addition, two glucosinolates have been identified in the root: sinigrin, which is also the characteristic aroma compound of black mustard and horseradish, and glucocochlearin, found in trace quantities. These tasteless compounds are enzymatically hydrolyzed to the pungent “mustard oils” allyl isothiocyanate and *sec*-butyl isothiocyanate, respectively. Further trace components are 6-methylthiohexyl isothiocyanate, 7-methylthioheptyl isothiocyanate and 8-methylthiooctyl isothiocyanate. These compounds are generally classified as *omega*-methylthioalkyl isothiocyanates.

[0024] One preferred form to include wasabi in the formulations of the present invention is wasabia japonica root extract, which can be obtained from Active Concepts, LLC in S. Plainfield, New Jersey. The wasabia japonica root is extracted using a method proprietary to Active Concepts that involves the following general methods: fermentation of the dry plant matter in water; initial extraction using a potassium phosphate aqueous solution; and separation of all molecular fractions below 5,000 MW using a tangential flow filtration method to provide the commercial material. Other methods of manufacturing wasabi extract include enzymatic extraction or sequentially macerating plant matter in water or other solvents and then percolating the plant matter in a solvent extraction process.

[0025] Despite the effectiveness of wasabi as a preservative, it has been determined that it is most effective when utilized in combination with at least one co-preservative. The use of a co-preservative is advantageous because it enables the use of lower wasabi concentrations than might otherwise be required to control microbial growth. When high wasabi concentrations are required to preserve a product, skin irritation with clinical manifestations, e.g. erythema, and/or sub-clinical manifestations, e.g. itching, is possible. The use of co-preservatives thus allows the selection of an optimized wasabi concentration that balances the desired preservative action with minimized skin irritation.

[0026] One such co-preservative is pentylene glycol ( $C_5H_{12}O_2$ ), an organic compound that is commercially available from Dragoco, Inc. in Totowa, New Jersey. Although pentylene glycol has been used in combination with chemical preservatives, such as parabens, its synergistic co-preservative effect with natural substances has not been heretofore established.

[0027] Another co-preservative is the combination of capryloyl glycine and undecylenoyl glycine. Glycines are amino acids commonly found in plants, and capryloyl glycine ( $C_{10}H_{19}NO_3$ ) is the acylation product of glycine with caprylic acid chloride. Undecylenoyl Glycine is the acylation product of glycine with n-undecylenoyl chloride. Both capryloyl glycine and undecylenoyl glycine are commercially available from SEPPIC, in Paris, France under the trade names Lipacide C8G and Lipacide UG, respectively.

[0028] Other suitable natural co-preservatives, including variations and derivatives of the foregoing, may also be used and are compatible with the present invention.

[0029] Suitable concentrations of wasabi to preserve personal care products ranges from a low of about 0.1 % to a high of about 10% by weight of the overall composition. Nevertheless, wasabi ranges substantially above about 5% may result in skin irritation, and therefore a preferred range is from about 3% to about 6% by weight of the composition. In the case of low water content formulations, which generally has a lower susceptibility to microbial growth or where wasabi may be used to boost the effect of other preservatives or co-preservatives, a lower range of wasabi is also effective, preferably from about 0.1% to about 1% by weight of the composition.

[0030] Suitable concentration ranges for co-preservatives will vary depending on the selected co-preservative, the concentration of wasabi, and the product being preserved.

#### B. VEHICLES

[0031] The systems of the invention can employ various vehicles, or mediums, depending on the particular form of personal care product. Common vehicles include solutions, emulsions, gels, and serums, each of which can be used to provide the desirable form for consumer products, such as toners, lotions, creams, cleansers, refiners, and the like. These varied vehicles enable the present invention to be used in the wide range of personal care products that are commercially available.

[0032] Gels and serums are similar vehicles, the main difference being that gels tend to have a high viscosity whereas serums have a low viscosity. Oil and water emulsions can be either oil-in-water emulsions or water-in-oil emulsions, either one being suitable for use with consumer care products. However, the ratio of oil-to-water can greatly affect the concentration of preservatives required. This is because microbes tend to flourish or die, depending on the amount of water present in a formulation. Thus, an emulsion with 1% oil and 99% water generally requires higher concentrations of wasabi preservative than an emulsion with 99% oil and 1% water. For example, an emulsion of 50% to 99% in the oil phase and 1% to 50% in the water phase may require wasabi in a concentration of from about 0.1% to about 5 % by weight of the composition, whereas an emulsion of 1% to 50% in the oil phase and 50% to 100% in the water phase may require wasabi in a concentration of from about 0.1% to about 10% by weight of the composition.

[0033] Typical components of the herein discussed vehicles (solutions, gels, serums, and emulsions) vary depending on the particular formulation, but may include water, emulsifiers, co-emulsifiers, thickeners, surfactants, gellants, humectants, moisturizers, botanicals, solubilizers, acidulents, neutralizers, emollients, organic sunscreens, inorganic powders, astringents, chelating agents, solvents, detergents, essential oils, and colorants.

[0034] In addition, it has been determined that the vehicles of the herein disclosed systems will preferably have a pH value in a range from about 2 to about 8, more preferably from about 3 to about 7, and most preferably from about 5 to about 6.

[0035] Methods of preserving personal care products involves the application of the foregoing teachings regarding the use of wasabi preservative compositions to inhibit microbial growth in personal care products. Hence, the methods involve mixing the

appropriate amounts of wasabi and the desired co-preservative into the chosen vehicle of the personal care product, such as solutions, gel, serum, or emulsion. Other packaging techniques (sealed containers, sanitary pumps) may also assist in inhibiting microbial growth.

[0036] The following examples are given to illustrate the present invention, and are not intended to limit the scope of the invention.

#### EXAMPLES

[0037] Ten consumer product formulations were prepared according to the foregoing teachings to incorporate the use of wasabia japonica root extract as a preservative. These formulations are presented in the following Examples 1-10. The concentrations are in weight percent.

[0038] Example 1: Day Energy Serum

COMPONENT	PERCENT
Water	76.6270
Wasabia Japonica Extract	5.0000
Glycerine	2.5000
Dimethicone	2.5000
Pentylene Glycol	2.0000
Methyl Gluceth-20	1.5000
Polysorbate-20	0.5000
Xanthan Gum	0.3000
Carbomer	0.1500
Sodium Hydroxide	0.0520
Tetrasodium EDTA	0.0500
Others	8.8210
Total	100.0000

[0039]

Example 2: Night Recovery Serum

COMPONENT	PERCENT
Purified Water	65.3190
Glycerine	7.0000
Cyclomethicone/Dimethicone/Phenyl Trimethicone	7.0000
Butylene Glycol	5.0000
Wasabia Japonica Root Extract	5.0000
Dimethicone Copolyol	2.0000
Cyclomethicone	2.0000
Pentylene Glycol	2.0000
Polysorbate 20	0.8500
Xanthan Gum	0.2500
Carbomer	0.1500
Tetrasodium EDTA	0.0500
Sodium Hydroxide	0.0400
Others	3.3410
Total	100.0000

[0040]

Example 3: Hydrating Refiner

COMPONENT	PERCENT
Purified Water	89.3240
Wasabia Japonica Root Extract	3.5000
Polysorbate-20	0.9000
Pentylene Glycol	0.8900
Benzophenoneone-4	0.0500
Tetrasodium EDTA	0.0450
Others	5.2910
Total	100.0000

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SALT LAKE CITY, UTAH 84111

[0041]

## Example 4: Mattefying Refiner

COMPONENT	PERCENT
Purified Water	89.5350
Wasabia Japonica Root Extract	3.5000
Polysorbate-20	1.5000
Pentylene Glycol	1.5000
PEG-40 Hydrogenated Castor Oil/Trideceth-9	.6000
Benxophenone-4	.0500
Tetrasodium EDTA	.0500
Others	3.2650
Total	100.0000

[0042]

## Example 5: Day Veil Crème

COMPONENT	PERCENT
Purified Water	45.8590
Cyclopentasiloxane Dimethicone/Vinyl Dimethicone Crosspolymer	12.0000
Ethylhexyl Methoxycinnamate	6.0000
Glyceryl Stearate	6.0000
PEG-40 Stearate	3.5000
Butylene Glycol	2.0000
Pentylene Glycol	1.0000
Stearic Acid	2.5000
Glycerin	2.0000
Cetyl Octanote	2.0000
Cyclomethicone	1.5000
Dimethicone	1.5000
Titanium Dioxide	1.0000
Sodium Carbomer	0.3500
Wasabia Japonica Root Extract	0.3000
Chlorphenesin	0.2000
Methylparaben	0.2500
Disodium EDTA	0.0500
Others	11.9910
Total	100.0000

[0043]

## Example 6: Night Nourishing Crème

COMPONENT	PERCENT
Purified Water	61.5530
Cyclopentasiloxane Dimethicone/Vinyl Dimethicone Crosspolymer	14.0000
Pentylene Glycol	3.0000
Cetyl Octanoate	2.0000
Dimethicone	2.0000
Ethylhexyl Methoxycinnamate	1.5000
Sodium Carbomer	0.5000
Acrylates/C10-30 Alkyl Acrylate Crosspolymer	0.5000
Wasabia Japonica Root Extract	0.3000
PEG-75	0.2500
Chlorphenesin	0.2000
Methylparaben	0.2500
Tetrasodium EDTA	0.0500
Others	13.8970
Total	100.0000

[0044]

## Example 7: Night Nourishing Lotion

COMPONENT	PERCENT
Purified Water	65.5530
Isohexadecane	6.5000
Wasabia Japonica Root Extract	5.0000
Pentylene Glycol	3.0000
Cyclopentasiloxane	3.0000
Hydrogenated Polyisobutene	2.5000
Ethylhexyl Methoxycinnamate	0.5000
Laureth-7/ Polyacrylamide /C13-14 Isoparaffin / Water	0.5000
Acrylates / C10-30 Alkyl Acrylate Crosspolymer	0.4000
Sodium Hydroxide	0.1000
Xanthan Gum	0.1500
Tetrasodium EDTA	0.0500
Others	12.7470
Total	100.0000

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A PROFESSIONAL CORPORATION  
ATTORNEYS AT LAW  
1000 EAGLE GATE TOWER  
60 EAST SOUTH TEMPLE  
SALT LAKE CITY, UTAH 84111



[0045]

Example 8: Day Veil Lotion

COMPONENT	PERCENT
Purified Water	58.5390
Cyclopentasiloxane Dimethicone/Vinyl Dimethicone Crosspolymer	10.0000
Ethylhexyl Methoxycinnamate	6.0000
Glyceryl Stearate SE	3.0000
Stearic Acid	2.5000
Butylene Glycol	2.0000
Glycerin	2.0000
Pentylene Glycol	1.0000
Titanium Dioxide	1.0000
Wasabia Japonica Root Extract	0.3000
Carbomer	0.2500
Chlorphenesin	0.2000
Methylparaben	0.1900
Sodium Hydroxide	0.0400
Others	12.9810
Total	100.0000

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[0046]

Example 9: Creamy Cleanser

COMPONENT	PERCENT
Purified Water	62.7290
Canola Oil	8.0000
C12-15 Alkyl Benzoate	5.0000
Glycerin	2.6000
Pentylene Glycol	2.6000
Glyceryl Stearate and PEG-100 Stearate	2.5000
Stearic Acid	2.0000
Polysorbate 20	2.0000
Capryloyl Glycine	1.0000
Euphorbia Cerifera (Candelilla) Wax	1.0000
Cetyl Alcohol	0.9500
Sodium Hydroxide	0.5400
Undecylenoyl Glycine	0.5000
Ethylhexyl Methoxycinnamate	0.5000
Citric Acid	0.5000
Xanthan Gum	0.4000
Wasabia Japonica Root Extract	0.3000
Carbomer	0.2000
Sodium Metabisulfite	0.0500
Tetrasodium EDTA	0.0500
Others	6.5810
Total	100.0000

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[0047]

Example 10: Foaming Cleanser

COMPONENT	PERCENT
Purified Water	31.3340
Sodium Lauroyl Oat Aminoacids	20.0000
PEG-120 Methyl Glucose Dioleate	5.0000
Cocamidopropyl Betaine	3.5000
Decyl Glucoside	3.0000
Pentylene Glycol	1.0000
Vegetable Glycerin	1.5000
Capryloyl Glycine	1.0000
Undecylenoyl Glycine	0.5000
Sodium Hydroxide	0.6200
Wasabia Japonica Root Extract	0.3000
PEG-75	0.2500
Polysorbate 20	0.2000
Citric Acid	0.5000
Benzophenone-4	0.1000
Tetrasodium EDTA	0.0500
Others	31.1460
Total	100.0000

[0048] The effectiveness of the above formulations was challenge tested according to USP 24 guidelines. The specified method comprised the basic steps of: (1) sterilizing a sample; (2) inoculating each formula sample with the micro-organisms as specified by the USP 24; (3) analyzing the sample at intervals of 0, 7, 14, 21, and 28 days to quantify the test substance; and (4) validating the counting procedure. Challenge testing under USP 24 guidelines prescribes that for a Category 1B product (e.g. Creamy Cleanser and Day Energy Serum), there be no less than a 2 log reduction from day 1 to day 14 and no increase in colony count from day 14 to day 28. Each of the above formulations satisfied the respective challenge test.

[0049] As indicated in each of Examples 11 and 12, these criteria were satisfied as to Creamy Cleanser and Day Energy Serum with each of the test substances staphylococcus

aureus ATCC 6538, escherichia coli ATCC 8739, pseudomonas aeruginosa ATCC 9027, candida albicans ATCC 10231, and aspergillus niger ATCC 16404.

**[0050]** Example 11: Preservative Challenge for Creamy Cleanser

Test Substance	Initial	Day 7	Day 14	Day 21	Day 28
Staphylococcus aureus ATCC 6538	3.2e5	700	<10	<10	<10
Escherichia coli ATCC 8739	3.2e5	4200	<10	<10	<10
Pseudomonas aeruginosa ATCC 9027	6.2e5	<10	<10	<10	<10
Candida albicans ATCC 10231	6.6e5	300	5000	<10	<10
Aspergillus niger ATCC 16404	2.9e5	<30,000	7000	<10	<10

**[0051]** Example 12: Preservative Challenge for Day Energy Serum

Test Substance	Initial	Day 7	Day 14	Day 21	Day 28
Staphylococcus aureus ATCC 6538	3.2e5	<10	<10	<10	<10
Escherichia coli ATCC 8739	3.2e5	<10	<10	<10	<10
Pseudomonas aeruginosa ATCC 9027	6.2e5	<10	<10	<10	<10
Candida albicans ATCC 10231	6.6e5	<10	<10	<10	<10
Aspergillus niger ATCC 16404	2.9e5	9300	400	<10	<10

**[0052]** The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing

description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

[0053] What is claimed is:

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A PROFESSIONAL CORPORATION  
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SALT LAKE CITY, UTAH 84111